

004	PRE- MARKET NOTIFICATION	RÖSCH
Dr. Zalewski	510(k) Summary	Rösch AG Medizintechnik
05.09.2002	(As required by 21 CFR 880.5430)	

Page 1 / 1

A Submitter Information

Rösch AG Medizintechnik
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K020786

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Contact: Dr.-Eng. Kerstin Zalewski
Head of Regulatory Affairs
Date: July, 22nd, 2002

SEP 25 2002

B Device Information

Trade/ Proprietary Name:

INJEX™ needle- free injection system *Extra*
ROJEX™ needle- free injection system *Extra*

Common Name of device:

Jet Injector

Classification Name:

Fluid Injector, non- electrically powered

C Predicate Device(s):

Hypex Jet Injector, Medi-Jector Choice, INJEX 50 System,
Jet Syringe

Predicate 510(k) #:

K945873; K962956, K003864, K003741

D Device Description:

The INJEX™ and ROJEX™ Systems *Extra* are medical devices to apply liquid medicine needle- free through the skin into the subcutaneous tissue. The process is based on the generation of a defined high velocity jet of fluid to penetrate the skin and to transport the medicine to the subcutaneous tissue. The energy source to accelerate the fluid within the ampoule is an internal spring.

The INJEX™ Injector is designed for multi- use. To tense the spring within the small hand- held injector for injection the reset box is used. For patient's safety the injector is equipped with two safety mechanisms. The automatic mechanism will be deactivated by mounting the ampoule onto the injector, and before injecting the dose of medicine to the individual the safety ring needs to be released.

The ROJEX™ Injector is a disposable medical device for single- use. For patient's safety the injector is equipped with a manual safety mechanism, the safety ring. Before injecting the dose of medicine to the individual the safety ring needs to be shifted into the safe- off position.

To transfer the medicine from its different repositories into the ampoule several adapters are designed. In case, medicines in cartridges are used an aid is available: the transporter.

The INJEX™ Systems *Extra* consist of two main components which are re- usable:

- INJEX™ Injector
- Reset Box

The ROJEX™ Systems *Extra* represent the disposable medical device:

- ROJEX™ Injector, pre- tensed

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The three accessories for INJEX™/ ROJEX™ needle- free Injection systems *Extra* are:

- Transporter, re- usable
- Adapter, sterile, usable for one medicine repository
- Ampoule, sterile, for single- use

E Intended Use:

The INJEX™ - and ROJEX™ needle- free injection systems *Extra* are designed for the delivery of medicines which are administrated subcutaneously by jet injection. Because of the absence of a needle, the fluid is transferred from an ampoule via its mirco- orifice through the skin with the aid of a capillary, high velocity jet to the body.

F Comparison of Required Technological Characteristics:

The INJEX™ - and ROJEX™ needle- free injection systems *Extra* picture the same technological characteristics as the predicated devices.

The key difference of the ROJEX™ injector is its mainly plastic composition and single- use mode. Both devices, INJEX™ - and ROJEX™ injectors, are suitable to deliver liquid pharmaceuticals into the subcutaneous tissue of the body.

Due to the technological identity and the same indications for use, no additional safety items had to be investigated.

G Summary and Conclusions of non- clinical Tests

In addition to the supplier's raw material testing regarding the ampoule, biological effects as cytotoxicity, tissue irritation, systemic toxicity, and sensitisation were analysed.

The body contact of the ampoule is classified as short term (< 10 min) indirect contact (drug- mediated) to skin.

Conclusion

The investigation present that the INJEX™ - and ROJEX™ needle- free injections systems *Extra* are safe and effective for the intended use and substantially equivalent to the legally market predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2002

Mr. Mark Job
Responsible Third Party
TUV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K020786

Trade/Device Name: INJEX™/ROJEX™ Needle-free Injection System Extra
Regulation Number: 880.5430
Regulation Name: Non-electrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: September 9, 2002
Received: September 10, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

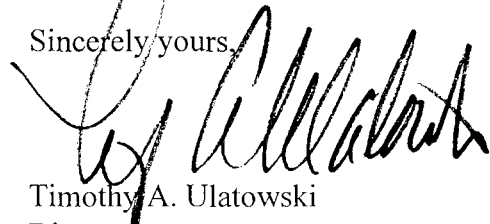
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Timothy A. Ulatowski', is written over the typed name and title.

Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Rösch AG Medizintechnik, Buckower Damm 114, 12349 Berlin, Germany

510(k) Number (if known): _____


Device Name: INJEX™/ ROJEX™ Needle- free Injection System Extra

Indications For Use:

The INJEX™- and ROJEX™ needle- free Injection System *Extra* is exclusively designed to deliver medicines that can be administrated subcutaneously by jet injection propelling a jet of liquid medicine through the skin into subcutaneous tissue under high pressure.

This medical device is intended for the application of prescription drugs and to sale by or on the order of a physician.

Target Population: Patients who have to be injected with liquid pharmaceuticals.


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 02 0286

Prescription Use ✓
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)